

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN**

ORTHO-McNEIL PHARMACEUTICAL, INC.,

Plaintiff,

v.

CARACO PHARMACEUTICAL
LABORATORIES, LTD.,

Defendant.

No. 2:04 CV 73698

Judge George Caram Steeh
Magistrate Judge Pepe

**STIPULATED ORDER TO BE BOUND AND
FOR PARTIAL STAY OF LITIGATION**

WHEREAS, in this action, plaintiff Ortho-McNeil Pharmaceutical, Inc. (“Ortho-McNeil”) charges defendant Caraco Pharmaceutical Laboratories, Ltd. (“Caraco”) with infringement of claim 6 of United States Patent No. 5,336,691 (“the ‘691 patent”) based on Caraco’s filing of an Abbreviated New Drug Application (“ANDA”) with the Food and Drug Administration (“FDA”) seeking permission to market a generic version of Ortho-McNeil’s Ultracet® drug product;

WHEREAS, in *Ortho-McNeil Pharmaceutical, Inc. v. Kali Laboratories, Inc.*, No. 02-CV-5707-JCL-MF (D.N.J.), pending before the United States District Court for the District of New Jersey, Ortho-McNeil charges Kali Laboratories, Inc. (“Kali”) with infringement of claim 6 of the ‘691 patent based on Kali’s filing of an ANDA seeking permission to market a generic version of Ultracet®;

WHEREAS, in *Ortho-McNeil Pharmaceutical, Inc. v. Teva Pharmaceutical Industries Ltd. et al.*, No. 04-CV-886-HAA-GDH (D.N.J.), pending before the United States District Court for the District of New Jersey, Ortho-McNeil charges Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc. (collectively “Teva”) with infringement of

claim 6 of the '691 patent based on Teva's filing of an ANDA seeking permission to market a generic version of Ultracet®;

WHEREAS the *Kali* and *Teva* cases are farther advanced than the present action;
and,

WHEREAS both Ortho-McNeil and Caraco seek to avoid litigating certain issues finally decided in *Kali* and/or *Teva* and unnecessarily expending the resources of this Court;

IT IS HEREBY STIPULATED AND AGREED, by and between Ortho-McNeil and Caraco, that this case shall be stayed in part, and the parties shall be bound to the outcome of *Kali* and/or *Teva* on issues of validity and enforceability, as described below:

1. Ortho-McNeil and Caraco hereby agree to be bound, on the ultimate issues of the validity and enforceability of claim 6 of the '691 patent, by final judgments (including any judgments on appeal) of *Kali* and *Teva*, and will waive, for purposes of this action, their rights to litigate those issues and any arguments going to those ultimate issues that were not made in those cases. (The parties agree to be bound to the extent ultimate determinations of validity and enforceability are so rendered, and not by any of the analysis or rationale underlying those determinations, including any ruling on claim construction.) If, after all appeals are exhausted, on the ultimate issues of the validity and enforceability of claim 6 of the '691 patent, at least one of the cases results in a final determination that claim 6 of the '691 patent is invalid and/or unenforceable, Ortho-McNeil and Caraco agree to be bound by that final judgment. If, after all appeals are exhausted, on the ultimate issues of the validity and enforceability of claim 6 of the '691 patent, at least one of the cases results in a final determination that claim 6 of the '691 patent is valid and enforceable, and there is no final determination in the other case

or the final determination in the other case is the same, Ortho-McNeil and Caraco agree to be bound by that final judgment. If both *Kali* and *Teva* conclude without any final determinations on the ultimate issues of the validity and enforceability of claim 6 of the '691 patent, Ortho-McNeil and Caraco agree that they must litigate the issues in this action after all. In any event, the parties will not be bound by the entry of a stipulated judgment on the issues of validity and/or enforceability and, rather, are agreeing to be bound only by a final judgment entered by a court on those issues.

2. The parties agree that claim 6 of the '691 patent remains valid and enforceable against Caraco unless and until the parties become bound by a final determination of invalidity and/or unenforceability in *Kali* and/or *Teva*, or no final determination is reached in *Kali* and *Teva* and Caraco successfully litigates the issues in this case.

3. In the event that either of the *Kali* or *Teva* district courts issues a final judgment that Claim 6 of the '691 patent is invalid and/or unenforceable, nothing in this agreement shall prevent Caraco from using that final judgment to secure a corresponding final judgment in this case on collateral estoppel grounds, and the 30 month stay shall immediately be lifted, regardless of whether said *Kali* or *Teva* judgment is appealed by Ortho-McNeil. Ortho-McNeil nevertheless retains the right to appeal such final judgment in this case on all available grounds, and Caraco retains the right to fully respond to any and all arguments advanced by Ortho-McNeil in any such appeal. The parties, however, hereby agree that the outcome of such appeal on the issues of validity and enforceability is governed by the outcome of the appeal(s) of the *Kali* and/or *Teva*

final judgments in the same manner as provided for in Paragraph 1 and they will not relitigate those issues.

4. Nothing in this agreement shall be construed to give Ortho-McNeil the right to an automatic preliminary injunction, although, while the parties await a final determination on the issues of validity and enforceability in *Kali* and *Teva*, Caraco has waived its right to challenge the validity or enforceability of Claim 6 of the '691 patent – in a preliminary injunction context or otherwise – other than on collateral estoppel grounds stemming from a final judgment from the *Kali* or *Teva* district courts. If, however, either of the *Kali* or *Teva* district courts issues a final judgment that Claim 6 of the '691 patent is invalid and/or unenforceable, nothing in this agreement shall prevent Caraco from arguing that Ortho-McNeil is unlikely to succeed on the merits of a preliminary injunction motion against Caraco on the grounds that Claim 6 of its patent is invalid and/or unenforceable based on the *Kali* or *Teva* judgment. To provide Ortho-McNeil an opportunity to seek a preliminary injunction, should it so desire, Caraco agrees to give Ortho-McNeil 45-days notice before it launches its generic version of Ultracet®.

5. Nothing in this stipulation affects or waives the parties' rights to continue to litigate the infringement issues, including infringement under the doctrine of equivalents. Neither party waives any argument whatsoever relating to the infringement question, including Caraco's argument that invalidity over the prior art precludes the application of the doctrine of equivalents. Neither party agrees to be bound in any way by the outcome in either *Kali* or *Teva* in connection with any infringement issue.

6. The parties agree to waive all further discovery relating solely to the validity and/or enforceability of the '691 patent. The parties agree to stay all expert discovery on infringement issues, except that the parties may submit expert reports and declarations in conjunction with Caraco's Motion for Summary Judgment of Non-Infringement. In the event that Caraco's Motion for Summary Judgment is denied, the stay of expert discovery shall be lifted as to infringement issues. This case shall thenceforth proceed to trial on issues of infringement alone.

7. Nothing in this stipulation shall be construed to affect, in any manner, the resolution of Caraco's Motion for Summary Judgment of Non-Infringement currently pending before the Court, or the timeliness of the resolution thereof.

8. Ortho-McNeil and Caraco agree to file this agreement with the Federal Trade Commission and the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice ("the Antitrust Agencies"), pursuant to Section 1112 of the Medicare Prescription Drug and Improvement Act, as promptly as practicable and in no event later than 10 business days after it is executed, and agree that this agreement shall be null and void if one of the Antitrust Agencies determines that the agreement violates antitrust law. The parties agree to coordinate and to respond promptly to any requests for additional information made by the Antitrust Agencies relating this agreement.

Respectfully submitted and stipulated,

ORTHO-McNEIL PHARMACEUTICAL,
INC.

CARACO PHARMACEUTICAL LABORATORIES,
LTD.

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Dated: September ___, 2005

SO ORDERED this 12th day of September, 2005

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s/George Caram Steeh
GEORGE CARAM STEEH
UNITED STATES DISTRICT JUDGE

CERTIFICATE OF SERVICE

Copies of this Order were served on the attorneys of record on September 12, 2005, by electronic and/or ordinary mail.

s/Marcia Beauchemin

Case Manager/Deputy Clerk